COLORADO MESA UNIVERSITY

**INFORMED CONSENT TO PARTICIPATE IN A MINIMAL RISK, NON-INTERVENTIONAL HIPAA RELATED RESEARCH PROJECT**

[You are encouraged to model your consent form after this consent form. If you choose not to use this format, your consent form must at a minimum include the same elements as this model and the required texts. Before using this model, remove all text in brackets. In addition, your consent form should be printed on university letterhead.]

TITLE OF PROJECT: [insert title here]

You are asked to participate in a research study conducted by [insert names and degrees of all investigators], from the [insert department] at Colorado Mesa University.

WHY SIGN THIS DOCUMENT?

To let the researchers from Colorado Mesa University (CMU) use and share your health information for this study, sign this document. We will give you a copy.

WHY ARE YOU ASKING FOR MY INFORMATION?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

WHAT INFORMATION WILL YOU USE AND SHARE FOR THE STUDY?

If you say yes, we will:

* Use and share information from [insert name of institution or organization].
* Use and share [describe in detail the information to be used].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

HOW WILL YOU USE AND SHARE THIS INFORMATION?

* We will use your information only for the study described in this document.
* We may share your information with [list anyone other than the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here].
* [*Note to researcher*: If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on [insert condition] so they can contact you about being in other research studies.]
* We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

WHAT HAPPENS IF I SAY NO?

We will not use or share your information for this study. The care you get from your doctor will not change.

WHAT HAPPENS IF I SAY YES, BUT CHANGE MY MIND LATER?

At any time, you can tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this, please ask. [*Note to researcher*: After permission is revoked, researchers are permitted to use and disclose health information in very limited circumstances that relate to protecting the integrity of the research. For example, such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.]

If you want us to stop, you have to tell us in writing. Write or e-mail [insert name and address and e-mail]. If you have questions, contact [insert name and phone # and e-mail].

If you stop, the care you get from your doctor will not change.

HOW LONG WILL MY HEALTH INFORMATION BE USED?

We expect our study to take at least [insert number] years. We will not use or share your information after the study is done [*Note to researcher*: If the information is being shared for any reason other than this research, that also requires a HIPAA authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

WHAT IF I HAVE QUESTIONS?

If you have any questions about the study, call the head of the study, [insert name and phone #]. Please call if you have:

* Questions about your rights.
* Questions about how we will use and share your information.

You can also call the office in charge of research at [insert phone#] to ask questions about this study.

By signing the document you are letting us use and share your health information for this study. [Add other uses and disclosures referenced above. For example: By signing the document you are giving us permission to contact you about being in other research studies.]

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Your name (Print)

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Your signature Date

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If an interpreter was used

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Signature of interpreter Date

If someone is signing this form for the subject, explain why:

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Name of legally responsible person (Print) Date

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Signature of person signing for the subject

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Relationship to the Subject Date

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Name of person conducting the consent discussion (Print)

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Signature of person conducting the consent discussion Date